REMARKS

For reasons set for below, all of the outstanding rejections in the application should be withdrawn, and the case passed to allowance.

I. STATUS OF CLAIMS AND EXPLANATION OF AMENDMENTS

Claims 1-3, 8, 11-14, and 55-60 were pending at the time that the action was issued.

In this paper, claim 1 was amended to incorporate a "95%" limitation from claim 56. Thus, this amendment does not introduce new issues, but it renders moot at least one rejection, as explained below.

Claim 1 also was amended to delete "fragment" language that the PTO had alleged to be indefinite. Thus, this amendment also does not introduce any new issues, but rather, renders moot at least one rejection.

Some of the dependent claims are amended to improve antecedent basis with respect to "nucleic acid molecule" as recited in claim 1.

II. CLAIM 60 SHOULD BE DEEMED ALLOWABLE.

Claim 60 should have been allowed because none of the alleged rejections are relevant to claim 60.

Claim 60 was rejected only under 35 USC §102, and the rejection was based on the premise that the claims are directed to "a nucleic acid molecule 'comprising' a sequence that encodes residues 128-224 of the amino acid sequence set-forth in SEQ ID NO:8 . . . ." Claim 60, however, is an independent claim that does not use "comprising." Rather, claim 60 specifies that the polypeptide "consists" of residues 128-224. The cited reference does not teach a polypeptide "consisting of" these residues or a nucleic acid sequence that encodes such a polypeptide. Thus, the rejection was improper, and claim 60 should have been allowed.

III. THE WRITTEN DESCRIPTION REJECTION IS RENDERED MOOT AND SHOULD BE WITHDRAWN.

The basis for rejection under 35 USC §112, first paragraph, is rendered moot by incorporation of limitations from claims that were not rejected.

The Patent Office rejected claims 1, 8, 11-14, 55, and 59 under 35 USC §112, first paragraph, alleging lack of written description. The rejection focused on claims with an "85% identity" limitation, and acknowledged that the case provides written description support for claims with a "95% identity" limitation. Claims 56-59, which had limitations of at least 95% identity, were not rejected.

To expedite allowance and render moot the rejection, the Applicants have amended claim 1 to include the "at least 95%" limitation from, e.g., claim 56. Accordingly, the rejection alleging lack of written description should be withdrawn.

IV. THE REJECTION UNDER 35 USC §112, SECOND PARAGRAPH, HAS BEEN RENDERED MOOT.

The Patent Office rejected claims 1, 8, 11-14, and 55-58 under 35 USC §112, second paragraph, alleging that it was unclear how a "fragment" of SEQ ID NO: 8 as recited in claim 1 can have less than 100% identity to SEQ ID NO: 8. All claims other than claim 1 were rejected because they depend from claim 1. To expedite allowance, the "fragment" language of claim 1 has been deleted, rendering moot the rejection based on a "comprising" construction.

V. THE REJECTION UNDER 35 USC §102(B) SHOULD BE WITHDRAWN.

The Patent Office rejected all of the pending claims under 35 USC §102(b), alleging anticipation by Rosen et al., WO 00/55175. The Applicants respectfully traverse. The Applicants respectfully disagree with the Patent Office's interpretation of the cited Rosen publication, and with the Patent Office's interpretation of the claims, and with the conclusion that the claims lack novelty.

A. Rosen fails to teach a polynucleotide satisfying the structural limitations of the claim.

Amended claim 1 specifies that the amino acid sequence of said polypeptide consists of a sequence that has at least 95% sequence identity with residues 128-224 of the amino acid sequence presented in SEQ ID NO: 8. The rejection is based entirely on a dubious claim construction and analysis of whether Rosen teaches a nucleic acid molecule "comprising" a sequence that encodes residues 128-224 of SEQ ID NO: 8. The amended claim specifies "consisting of" language, rendering moot the rejection based on the "comprising" claim construction.

Rosen fails to teach the specific fragment specified by claim 1. Rosen mentions in passing three small "preferred epitopes" at the bottom of page 14 and speculates, incorrectly, in Table 1 (page 74) residues 1-33 constitute a "signal peptide" and 34-216 constitute a mature sequence. However, Rosen fails to teach or suggest a fragment consisting of residues 128-224 of SEQ ID NO: 8, or a polynucleotide encoding such a fragment.

B. Rosen does not teach that SEQ ID NO: 36 interacts with p53.

The Patent Office is inappropriately interpreting Rosen by construing Rosen based on teachings in the present application. The Patent Office asserts that Rosen "teaches a nucleic acid molecule encoding a polypeptide (SEQ ID NO: 36) **[SIC: SEQ ID NO: 63]** which is a 217 amino acid fragment of instant SEQ ID NO: 8" and that "Rosen et al. further teaches said polypeptide would bind p53 (see page 14, in particular)." A person of ordinary skill, without the exercise of hindsight, would understand that Rosen is a "genomics" application that purports to teach *fifty* human "secreted" proteins (see, e.g., Title). In actuality, Rosen provides no meaningful guidance whatsoever about the biological activity of SEQ ID NO: 63 or the other purported gene products taught by Rosen. In addition to the single sentence at page 14 cited by the Patent Office, Rosen further discusses the "features" of the gene product at page 15, where Rosen speculates wildly about other possible activities:

> The secreted protein can also be used to determine biological activity, to raise antibodies, as tissue markers, to isolate cognate ligands or receptors, to identify agents that modulate their interactions, and as

> nutritional supplements. It may also have a very wide range of biological activities. Typical of these are cytokine, cell proliferation/differentiation modulating activity or induction of other cytokines; immunostimulating/immunosuppressant activities (e. g. for treating human immunodeficiency virus infection, cancer, autoimmune diseases and allergy); regulation of hematopoiesis (e. g. for treating anemia or as adjunct to chemotherapy); stimulation or growth of bone, cartilage, tendons, ligaments and/or nerves (e. g. for treating wounds, stimulation of follicle stimulating hormone (for control of fertility); chemotactic and chemokinetic activities (e. g. for treating infections, tumors); hemostatic or thrombolytic activity (e. g. for treating hemophilia, cardiac infarction etc.); anti-inflammatory activity (e. g. for treating septic shock, Crohn's disease); as antimicrobials; for treating psoriasis or other hyperproliferative diseases ; for regulation of metabolism, and behavior. Also contemplated is the use of the corresponding nucleic acid in gene therapy procedures. Protein, as well as, antibodies directed against the protein may show utility as a tumor marker and/or immunotherapy targets for the above listed tissues.

Rosen further speculates wildly about the possible activities of all 50 of the alleged secreted proteins at, e.g., pages 175-207 and 221-223. Absent hindsight, a person of ordinary skill would not select the single biological activity mentioned on page 14 and ignore the dozens of other speculated activities. Rosen should not be construed as teaching anything about Rosen's polypeptide, except perhaps teaching, incorrectly, that the polypeptide has a signal peptide and is secreted.

C. Rosen fails to teach, suggest, or enable the inhibitory activity required by the claims.

Claim 1 specifies that the polypeptide inhibits the apoptotic activity of p53. Even if Rosen is construed as suggesting that Rosen's full length protein "binds" p53, Rosen cannot be construed to teach, or enable, the inhibitory activity recited in Claim 1.

The Patent Office asserts that "Although Rosen et al does not specifically teach said polypeptide inhibits the apoptotic activity of p53, the claimed polynucleotide appears to be the same as the prior art, absent a showing of unobvious differences." In other words, although not explicitly stated, the Patent Office relies on principles of inherency to supply the missing elements of the claim.

The facts of this case do not support a conclusion of inherency, however. First, as previously established, Rosen's encoded polypeptide is NOT identical to the polypeptide taught in the application. Rosen's sequence diverges from the sequence in the application after position 190 or Rosen or position 317 of the present sequence. (See Applicant's Amendment filed in response to the first office action.) Rosen's sequence also lacks sequence upstream of position 128 of the current sequence.

Second, as explained above, Rosen fails to specifically teach or suggest the a sequence corresponding to the fragment that is currently being claimed. It is improper to base a rejection on inherent functional activity without first establishing that the prior art teaches a molecule having a structure that satisfies the structural limitations of the claims.

For all of these reasons, the rejection alleging anticipation should be withdrawn.

VI. CONCLUSION

For the foregoing reasons, the Applicants respectfully request entry of this amendment, withdrawal of all rejections or objections, and allowance of the claims as amended.

Dated: February 22, 2008

Respectfully submitted,

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